Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519923	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Riverton Memorial Hospital, Llc	1320 Bishop Randall Drive, Lander, WY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced complaint survey was performed on March 12, 2024, at Riverton Memorial Hospital (SageWest Lander). The laboratory was found to be out of compliance for the following condition level deficiencies: 42 C.F.R. 493.1100 Condition: Facility Administration 42 C.F.R. 493.1250 Condition: Analytic Systems
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of emergency release documentation, review of the interlaboratory variance report, review of the blood bank nightly inventory check, and interview, the laboratory failed to meet the condition of facility administration. The laboratory failed to segregate unacceptable (expired) units from the routine blood and blood product inventory to prevent the emergency release of expired units (Refer to D3021).
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility

	must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on review of the emergency release documentation, review of the interlaboratory variance report, review of the blood bank nightly inventory review, and interview with technical supervisor (TS) #2, the laboratory failed to store non-expired blood and blood products separately from expired blood and blood products. Findings: 1. Review of the emergency release documentation showed one unit of packed red blood cells (pRBC) was released and issued on December 9, 2023, to patient A. Review of the emergency release form showed the unit issued to patient A on December 9, 2023, expired on December 8, 2023. 2. Review of the interlaboratory variance report confirmed that an emergency released unit that expired on December 8, 2023, was issued to patient A on December 9, 2023. 3. Review of the "Blood Bank Emergency Release Procedure" showed the laboratory failed to include instructions prohibiting the release of expired blood and blood products. 4. Review of the "Blood Product Inventory" review showed the laboratory failed to include a check of the expired blood and blood products. The "Blood Product Inventory" review was updated on December 13, 2023 to include a check of expired blood and blood products. 5. Interview with the TS #2 on March 12, 2024, at 3:00 PM confirmed the laboratory failed to segregate unacceptable (expired) units from the routine blood and blood product inventory to prevent emergency release of expired units.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of procedures, patient charts, temperature logs, blood bank emergency release forms, blood bank refrigerator alarm checks, and observation of blood bank refrigerator, the laboratory failed to meet the condition of analytic systems. The laboratory failed to have a step-by-step procedure for emergency release of blood and blood products to include instructions prohibiting the release of expired blood and blood products (Refer to D5403); the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents (Refer to D5413); the laboratory failed to label the coagulation reagent with a preparation and expiration date (Refer to D5415); and the laboratory failed to perform and document quarterly alarm inspection checks for the blood bank refrigerator and plasma freezer (Refer to D5555).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual and interview with the technical supervisor (TS) #2, the laboratory failed to have a step-by-step procedure for emergency release of blood and blood products. Findings: 1. Review of the "Blood Bank Emergency Release" procedure showed no reference to expired blood and blood products. 2. Interview with the TS #2 on March 12, 2024 at 3:00 PM confirmed the laboratory failed to include a step-by-step procedure for expired blood and blood products in the "Blood Bank Emergency Release" procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, documentation of refrigerator temperatures, observation of reagent material stored in the refrigerator, and interview with the technical supervisor (TS) #2, the laboratory failed to follow the manufacturer's instructions for storage of reagent material for six of twelve testing days for March 2024. Findings: 1. Review of the manufacturer's instructions for Siemens Dade Innovin reagent revealed to "store at 2-8 degrees C....Do not freeze." 2. Review of the laboratory's daily temperature record log #1 showed a defined acceptable range of 1-6 degrees Celsius (C). Six of twelve testing days failed to meet the manufacturer's required 2-8 degrees C range. 3. Observation of the laboratory freezer showed 1 box of Siemens Dade Innovin reagent (lot # 4564642) currently in use in the laboratory. 4. Interview with the TS #2 on March 12, 2024 at 11:00 AM confirmed the laboratory failed to define and monitor the correct storage temperature of coagulation reagents according to the manufacturer's instructions. 5. The laboratory reports approximately 2200 coagulation tests annually.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of one of one opened bottle of Siemens Dade Innovin reconstituted reagent, review of manufacturer's inserts, and interview with technical supervisor (TS) #2, the laboratory failed to label the coagulation reagent with a preparation and expiration date. Findings: 1. Observation of the coagulation refrigerator showed one opened reconstituted bottle of Siemens Dade Innovin reagent with no preparation and expiration date. 2. Review of the Siemens Dade Innovin manufacturer insert revealed "stability after reconsituted 10 days (closed vial) 2-8 degrees Celsius." 3. Interview with TS #2 on March 12, 2024, at 11:00 AM confirmed the laboratory failed to include the preparation and expiration dates on the reconstituted reagent. 4. The laboratory results approximately 2200 coaguation tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Review of calibration verification records for two of two Siemens Dimension EXL chemistry analyzers and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify. Findings: 1. Review of the calibration verification

	records for 2022, 2023, and to date March 12, 2024 for sodium, potassium, and chloride showed the laboratory failed to preform a three point calibration procedure that included a minimal, mid-point, and maximum value. 2. Interview with the TS #2 on March 12, 2024 at 1:00 PM confirmed the laboratory failed to perform calibration verification to include minimal, mid-point, and maximum value for sodium, potassium, and chloride at least once every six months. 3. The laboratory reports approximately 10,000 sodium, potassium, and chloride tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 blood bank alarm checks, procedure for alarm checks, and interview with the technical supervisor (TS) #2, the laboratory failed to perform and document inspections of the alarm system. Findings: 1. Review of the 2023 and 2024 blood bank alarm check log showed one blood bank alarm checked performed October 2023 for the blood bank refrigerator and no alarm checks for the plasma freezer. 2. Review of the "Alarm Checks and Corrective Action" procedure showed, "The alarm on each product storage unit must be checked quarterly." 3. Interview with TS #2 on March 12, 2024 at 3:00 PM confirmed the laboratory failed to perform quarterly alarm checks on the blood bank refrigerator and plasma freezer. 4. The laboratory reports approximately 1000 blood bank tests annually.